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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/700,738
Filing Date: November 04, 2003
Appellant(s): POPE ET AL.

Kurt L Grossman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 15 July 2008, corrected 6 August 2008 appealing from the Office action mailed 25 February 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,501,665	JHUBOO	03-1996
6,485,465	MOBERG	11-2002
2003/0205587	TRIBE	11-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-3, 5-31, 46-67, 72-74, and 78 are rejected under 35 U.S.C. 103(a) as being anticipated by JHUBOO (US 5,501,665).

Regarding claims 1,13,46,55,74,78 Jhuboo (see Fig 2-4, 7 and 8) teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (8) including a housing (10) adapted to support a syringe (12) containing a plunger (18) moveable inside the syringe by pushing an end of a plunger with a pusher (14) to expel fluid from an outlet of the syringe into a fluid line (tube shown in Figure 2) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line; during the pumping sequence, using a sensor (36) to determine a first force value indicative of force in the fluid line at time T1; during the pumping sequence, determining a second force value indicative of force in the fluid line at time T2; and providing an indication of the occlusion if a relationship between the first and second force values departs from an expected slope relationship. Col 1 lines 33-44; Col 4 line 50; Col 5 line 5.

Jhuboo uses the terms "initial pressure" and "second pressure" in the description as mean pressures (Col 4, lines 55-65). Jhuboo does not disclose using "instantaneous force values" in his equations (note that force and pressure are interchangeable since the force is used to calculate the pressure, Col 4 at line 30). Jhuboo suggests using an

instantaneous force at Col 5, lines 40-52 and that it is known in the art to use either mean or instant force values to determine occlusions, Col 1 line 15-30. One of ordinary skill in the art at the time the invention was made would have expected the method of Jhuboo to perform equally well using an instantaneous force value since Jhuboo discloses that it would react faster to an obstruction. By using the English description of the formulae given in Col 1, the examiner believes one of ordinary skill in the art would understand the use of instantaneous forces.

Regarding claims 2, 14, 24 an alarm (see Step 134, Fig 8, Col 5 line 21) is triggered when an occlusion is detected; therefore a no-alarm condition indicates there is no occlusion

Regarding claims 3, 15, 57 a steady-state condition is determined (gradient constant S_0), see Col 5 line 30-39.

Regarding claims 16-18, the gradient constant is determined from the startup time period and startup fluid volume, since the gradient constant is a function of the flow rate, or a function of volume and time.

Regarding claims 5, 23, 48, 60 a window (time interval) is determined for T1 and T2

Regarding claims 6, 25, 56, 58, and 61 an expected slope relationship (gradient constant) is compared to the first and second force values

Regarding claims 7, 8, 10, 26, 27, 29, 50, 52, 62, 63, 65 a trial slope (and occlusion slope, or gradient constant) (flow rate) is determined using the first and second force values and compared to an occlusion slope

Regarding claims 9, 28, 47, 49, 51, and 64 the expected relationship is compared to the relationship between the first and second force values to determine if an occlusion exists.

Regarding claims 11, 21, 30, and 66 a time window is shifted to obtain an additional force value

Regarding claims 12, 31, and 67 the indication of occlusion is cancelled when the comparison between the trial slope and the occlusion slope (or gradient constant) are compared

Regarding claims 19, 20, 22, 59 a sensor (force transducer 36) is used to determine the first and second force values.

Regarding claims 53, 54, 72, and 73, a third pressure measurement after time T3 is taken to be compared to the first two measurements.

2. Claims 32, 34, 36, 68, 70, 76, 77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13, 55, 74 and 78 above, and further in view of Tribe.

As disclosed above, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss altering the fluid flow rate beyond the indication to the user that an occlusion exists via an alarm.

Tribe teaches that an automatic syringe pump can be controlled by an occlusion detector to reverse the flow rate and require manual restart of the pump after an occlusion has occurred (P0005-0009).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the automatic fluid delivery rate controls of Tribe in order to make the pump easy to use and to prevent the user from either ignoring or failing to response to the alarm signals.

3. Claims 33, 35, 69, 71, 75, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13, 40, 55, 74 and 78 above, and further in view of MOBERG (US 6,485,465).

Regarding claims 33, 35, 69, 71, 75, and 79, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss the delivery of a bolus from the infusion pump; however any syringe pump is capable of bolus delivery.

Moberg teaches an infusion pump (101) and force occlusion detector (134). Moberg teaches that the occlusion detector automatically responds to force greater than the maximum allowable bolus delivery (Col 6 3rd paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the bolus occlusion detection of Moberg in order to prevent a false occlusion alarm resulting in the delivery of a prescribed bolus dose.

(10) Response to Argument

A. Jhuboo renders obvious the claimed invention

Appellant groups claims 1, 13, 46, 55, 74, and 78 (independent) with specific mention of claims 3, 15 and 55 (dependent). All of these claims have been rejected under 103(a) under Jhuboo alone

1. Overview

Appellant notes that Jhuboo teaches using mean pressures instead of instantaneous pressures in calculating his comparison slope S (see Fig 7, Col 5 line 5). Appellant's occlusion formula is essentially $F_2 - F_1 / T_2 - T_1$ compared to S_0. Jhuboo's formula is the exact same except that F_2 and F_1 are mean forces instead of instant forces. See Fig 8, Col 5 line 5, Col 4 line 50, and bottom of Col 1. Note that Jhuboo's "gradient constant" is the same as appellant's expected slope (Col 4 line 50 and Fig 7). Appellant argues that setting Δt equal to zero (Δt being the time the mean force F_1 or F_2 is determined over, see Col 4 line 55-65) would destroy the function of Jhuboo. First, there is an important distinction between setting Δt equal to zero and using instant force values. **If Jhuboo is altered to use instant force values than there is no Δt at all in the equations**. Appellant argues that it would not be obvious to change the teachings of Jhuboo because the only motivation would be hindsight reasoning. First, Jhuboo expressly discloses that it is known in the syringe pump occlusion detection art to use instant forces when there is low noise. Jhuboo notes that in the art workers may chose to use either instant or mean forces depending on the sensitivity of the occlusion levels (see Col 1 lines 15-30). Clearly, it not based on hindsight reasoning to use instant pressures when Jhuboo has expressly disclosed the use of instant pressures in the prior art and in the field of the invention in general.

2. Examiner's rejection of the Independent Claims

a. Jhuboo works correctly during normal operations

Here appellant argues that Jhuboo fails to correctly detect occlusions during operation. Not only does this directly contradict appellant's earlier statement that Jhuboo works perfectly well and should not be modified (see brief page 15, last paragraph) but is also irrelevant to the rejection.

b. Jhuboo works correctly at instantaneous or near instantaneous force values

Appellant argues that Jhuboo would not work at instantaneous force values. The examiner notes that the appellant has not argued anywhere in the brief that modified Jhuboo and the present claims differ in any way. If modified Jhuboo is inoperable, than how is the claimed invention operable? Second, Jhuboo does expressly teach using near instant force values. See Col 2 line 25, Col 5 line 45, and Col 5 line 47-50, all stating that Δt may be adjusted to increasingly smaller intervals based on the noise of the system. Finally, the use of Jhuboo at near instant forces is not especially relevant to the rejection because if Jhuboo is modified to use instant force values than there is no Δt at all in the equations.

c. Support for findings of obviousness to modify Jhuboo

Appellant addresses Jhuboo's teaching of the prior art using instantaneous forces at Col 1 lines 16-27. Appellant argues that Jhuboo's description does not teach exactly the same thing as the claims. While true, appellant does not recognize that Jhuboo teaches occlusions may be detected using *either* instant or average pressure, based on the desired sensitivity of the occlusion alarm. Jhuboo's English language

description of the formula (Col 1) and the mathematical description (Col 5 line 5) would suggest to one of ordinary skill in the art that *either* instant or average forces may be used to compare to the gradient constant.

d. Jhuboo does not teach away from the claimed invention

See (b) above. Appellant again argues that Jhuboo would not work at instantaneous force values. The examiner notes that the appellant has not argued anywhere in the brief that modified Jhuboo and the present claims differ in any way. If modified Jhuboo is inoperable, than how is the claimed invention operable?

i. Δt Optimization

Jhuboo teaches that Δt may be made increasingly smaller. Also, arguments relating to Δt are essentially irrelevant since modified Jhuboo has no Δt.

ii. Noise

Again, Jhuboo expressly teaches a smaller Δt for low noise systems: Col 2 line 25, Col 5 line 45, and Col 5 line 63.

iii. Ballooning perfusion rates

Appellant again argues that Jhuboo would not work at instantaneous force values. The examiner notes that the appellant has not argued anywhere in the brief that modified Jhuboo and the present claims differ in any way. If modified Jhuboo is inoperable, than how is the claimed invention operable?

3. Dependent claims 3, 15, and 57

Appellant argues that Jhuboo does not teach determining a steady state condition. First, no definition of “steady state” or “steady state condition” is given in the

specification. P0065 and 0059-0067 simply describe one example of how the applicant would determine when a "steady state" occurs. See Jhuboo Col 5 lines 30-40, which expressly teaches determining baseline gradient constants for later comparison. The examiner finds that this meets the claim language, which is simply "further comprising determining a steady state condition." This claim does not import any special definitions or any limitations from the specification as argued, such as being in a "live system" or that "a steady state condition" is different or excluded from a predetermined value. The phrase "determining a steady state condition" would be interpreted by one of ordinary skill in the art to include deducing or determining predetermined parameters such as the gradient constant.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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